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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,788	03/08/2001	Naoto Akiyama	Q63269	4071

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Washington, DC 20037

EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 07/09/2003 9

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/800,788

Applicant(s)

AKIYAMA ET AL.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/7/03 (Response to Restriction).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 13-35, 37 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 36 and 39-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 July 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. The Applicant's election without traverse of Group I., claims 1-12, 36 and 39-41 in Paper No. 8 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 39 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

Claim 9 is unclear because the circuits claimed do not correspond with the specification and the figures.

- As to claim 9, lines 7-20, confusion is created as two inductors (105, 110) are shown in the circuit diagrams yet only a single inductor is claimed.
- As to claim 9, lines 7-11 (the closed circuit of figure 2 associated with the first phase waveform), the second switching means (102) is not claimed as forming the closed circuit yet the means (102) appears to play a critical role in controlling the circuit.
- As to claim 9, lines 12-16 (the closed circuit of figure 3a), the third switching means (103) is not claimed in the closed circuit yet the means (103) appears to play a critical role in controlling the circuit.
- As to claim 9, lines 17-20, (apparently relating to figure 4) the third (103) switching means and the diode (108) are not claimed though both appear to play a critical role in

the functioning of the apparatus (figure 3(a), 3(b) and 4). For examination purposes, the Examiner reads claim 9 as an apparatus including an inductor, an electrical energy storage section, and a switching means.

Claim 39 is unclear because "an external type", does not define the object. For examination purposes, the Examiner reads the claim to be --an external type defibrillator--.

Claim 41 is unclear because "repeating a plurality of times" does not define what is repeated. For purposes of examination, the Examiner reads the claim to repeatedly apply a biphasic waveform to the patient.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-12, 36, and 39-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Lyster et al. (US 6405081). Lyster et al. disclose a biphasic energy delivery circuit for a defibrillator comprising a controller (26), an energy storage section (20), output electrodes (16), a means for reversing polarity (15) (col. 5 @ 15-19), a voltage measuring circuit (62), a current measuring circuit (60), an inductor (54) and switch means (28). A patient dependent parameter is used to control the pulse phases (figure 5; col. 1 @ 57-65; col. 2 @ 45-63; col. 5 @ 46-51).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint Inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. The Applicant is advised of the obligation under 37 CFR 1.56 to point out the Inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-12, 36 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan et al. (US 5222492) in view of Cameron et al. (US 5607454).

Morgan et al. disclose a cardiac defibrillator comprising a control circuit (20), a voltage generator (12), an electrode energy storage section (16), and an output electrode (52a, 52b) (col. 6 @ 17-27; col. 7 @ 10-13). Current (64) or voltage (72) measurements are used to control the energy transfer circuit (40) (col. 5 @ 18 – col. 6 @ 9). A shunt (56) or inductor is provided in the energy transfer circuit (col. 4 @ 55-59). Polarity switching is disclosed (col. 7 @ 10-13). The switches in the energy transfer storage section are semiconductors (col. 2 @ 6-10).

As discussed in the previous paragraph of this action, Morgan et al. disclose the claimed invention except for:

- the waveform being biphasic/multiphasic (claims 1, 2, 40 and 41),
- a means for reversing the polarity of the voltages outputted to the output electrode (claims 1 and 2),
- the energy output not depending on impedance and the energy output changing as a function of the predetermined time period (claims 3, 4, 6, 7 and 8), and
- a patient parameter measuring means (claim 8).

Cameron et al. disclose an electrotherapy method and apparatus and teach the following elements combinable, for the reasons noted, to modify the cardiac defibrillator as taught by Morgan et al.:

- the waveform being biphasic/ multiphasic (claims 1, 2, 40 and 41) to provide a lower energy waveform that enables the required size, cost, weight and components of the defibrillator to be reduced or changed, positively impacting the availability and operability of the apparatus (col. 2 @ 3-8; col. 3 @ 24-30; col. 11 @ 12-15).
- a means for reversing the polarity of the voltages (34) outputted to the output electrode (claims 1 and 2) to provide a means to create the biphasic pulses that improves the operability of the apparatus (col. 3 @ 24-30; col. 6 @ 4-11), and
- the energy output not depending patient impedance but rather time to deliver a charge (col. 7 @ 7-11), and the energy changing as a function of the predetermined time period

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(claims 3, 4, 6, 7 and 8) using a patient parameter from a patient parameter measuring means (claim 8) to optimize the defibrillation waveform for the patient (col. 5 @ 53-59; col. 6 @ 4-29; col. 7 @ 5-13).

Drawings

6. Figure 10(a), 10(b), 11(a), and 11(b) should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Figures 1, 2, 3(a), 3(b), 4, 5 and 7 are objected to under 37 CFR 1.83(a) because the rectangular boxes are not labeled as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

7. The disclosure is objected to because wording of the first paragraph on page 8 and the third paragraph on page 9 is awkward. Appropriate correction is required.

Abstract

8. The abstract of the disclosure is objected to because the abstract should generally describe the disclosure, assisting the readers in deciding whether there is a need for consulting the full patent text for details. The current abstract describes different circuits used to deliver the phases of the waveform and does not provide a general overview of the invention.

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The Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc. Correction is required. See MPEP § 608.01(b).

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

6/25/03

Angela D. Sykes

ANGELA D. SYKES
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